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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/05/2004

LS

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,331

Applicant(s)

STUIVER ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8 and 15-21 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3-8 and 15-21 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 19 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Office action is in response to the Amendment and Remarks filed 15 July 2003.
2. Claims 2 and 9-14 have been cancelled; new claims 16-21 have been entered.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3 and 15-21 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 is rejected for lack of written description because it contains New Matter. The limitation "are at least 5% in all plant parts" lacks adequate written description support in the specification and in the original claims (see page 10, 1st paragraph of the specification).

Applicant claims a plant promoter comprising a minimal promoter and two transcription-activating elements from different promoters that produce complementary expression patterns.

Applicant describes a plant promoter comprising a ferredoxin and a RoID promoter transcription-activation elements operably linked to a minimal promoter (the elected invention, see for example Figure 1).

Applicant does not describe the genus of transcription-activating elements that can be operably linked to a minimal promoter to produce complementary expression patterns.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed.

See MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. In the instant case Applicant does not adequately describe transcription-activating elements that can be used in conjunction with a minimal promoter that have complementary expression patterns as broadly claimed.

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7. Claims 1, 3 and 15-21 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a plant promoter comprising a ferredoxin and a RoID promoter transcription-activation elements operably linked to a minimal promoter, does not reasonably provide enablement for any plant promoter comprising a minimal promoter and two transcription-activating elements from different promoters that produce complementary expression patterns. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a plant promoter comprising a minimal promoter and two transcription-activating elements from different promoters that produce complementary expression patterns.

Applicant teaches a plant promoter comprising a ferredoxin and a RoID promoter transcription-activation elements operably linked to a minimal promoter (the elected invention, see for example Figure 1).

Applicant does not teach the genus of transcription-activating elements that can be operably linked to a minimal promoter to produce complementary expression patterns.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

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the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance on how to make and use a plant promoter comprising a minimal promoter and two transcription-activating elements from different promoters that produce complementary expression patterns. Applicant provides only one working example of the claimed invention that being a plant promoter comprising a ferredoxin and a RoID promoter transcription-activation elements operably linked to a minimal promoter.

The art teaches that transcription-activating elements of one promoter can act as a transcription-repressor in another promoter (see Fiedler *et al* 1993, Plant Molecular Biology 22: 660-679, see for example the Abstract on page 669). Fiedler *et al* teach that the role of a motif can only be disclosed by a closely confined change in sequence (page 674, left column, 1st paragraph). The art teaches that a transcription-activating element from one promoter may produce unpredictable results when operably attached to a non-homologous minimal promoter. Puente *et al* 1996 (The EMBO Journal 15(14): 3732-3743) teach that the GT1 motif of the *rbcS-3A* promoter and the Z motif of the *Arabidopsis cab1* promoter, when operably linked to a NOS101-GUS reporter construct exhibit higher GUS activity in dark-grown seedlings than in light-grown seedlings (page 3734). Given Applicant's limited guidance, the nature of the invention, the state of the prior art, the relative skill of those in the art and the unpredictability of the art, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use plant promoters comprising at least two

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transcription-activating elements from different promoters operably linked to a minimal promoter wherein said elements have complementary expression patterns as broadly claimed.

8. Claims 1, 3, and 15 remain rejected and claims 16-18 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 27 February 2002. Applicant's arguments filed 15 July 2003 have been fully considered but they are not persuasive.

Claim 1 remains rejected as indefinite because the limitation "complementary expression pattern" does not state the metes and bounds of the claimed invention. As taught above, the "expression pattern" of a transcription-activating element can be different when operably linked to a heterologous minimal promoter, hence, the instant limitation is indefinite. Applicant argues that the specification teaches that complementary expression patterns can exist when expression occurs in the same plant tissue, wherein the expression pattern of the first promoter and the expression pattern of the second promoter are at least 1% in all plant parts in which the first and second promoters overlap (page 9 of the response). This argument is not found to be persuasive for the reason given supra. It is clear from the teaching of the art that a transcription-activating element's expression pattern is relative to the promoter background to which it is operably associated.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "complementary expression patterns", and the claim also recites, "expression pattern...are at least 1%" which is the narrower statement of the range/limitation.

Claims 3, 15-18 and 21 are also indefinite because they do not obviate the indefiniteness of claim 1 upon which they depend.

Claim Rejections - 35 USC § 102

9. Claims 1, 3, and 15 remain rejected and claims 16-18 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gelvin *et al* (WO 95/14098, published 26 May 1995), as evidenced by Kononowicz *et al* 1992 (The Plant Cell 4:17-27). This rejection is repeated for the reason of record as set forth in the last Office action mailed

27 February 2002. Applicant's arguments filed 15 July 2003 have been fully considered but they are not persuasive.

Applicant argues that claim 1 recites that the transcription-activating elements from the first promoter and the transcription-activating elements from the second promoter have complementary expression patterns in the plant, and that the specification defines "complementary" as one promoter shows little overlap with the expression pattern of the other promoter. Applicant also argues that the expression patterns of the *ocs* and the *mas* promoters are not complementary (page 14 of the response). This argument is not found to be persuasive because claim 1 also indicates that said promoter expression patterns are at least 1% in all plant parts in which they overlap. The Examiner interprets this limitation to encompass 1% to 100%, hence the *ocs* and the *mas* promoters meet this limitation of the claims.

10. Claims 1, 3, 15-18 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Puente *et al* 1996 (The EMBO Journal 15(14): 3732-3743).

Puente *et al* disclose a plant promoter comprising a minimal CaMV 35S promoter operably linked to the GT1 transcription-activating element of the *rbcS-3A* promoter or the Z transcription-activating element of the *Arabidopsis cab1* promoter (page 3735, left column). Puente *et al* disclose that the 35S minimal promoter inherently comprising a transcription-activating element that directs expression in roots, and that the GT1 transcription-activating element of the *rbcS-3A* promoter or the Z transcription-activating element of the *Arabidopsis cab1* promoter direct expression in green tissues. Puente *et al* disclose a gene construct comprising said plant promoter operably linked to a GUS

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encoding sequence and plants transformed therewith. Puente *et al* disclose a plant promoter comprising a minimal NOS101 promoter operably linked to the GT1 transcription-activating element of the *rbcS*-3A promoter or the Z transcription-activating element of the *Arabidopsis cab1* promoter, and the G transcription-activating element of the *Arabidopsis cab* promoter or the GATA transcription-activating element of the *Arabidopsis rbcS* promoter (pages 3733-3734). Puente *et al* disclose that in the context of the NOS101 minimal promoter the GT1 or the Z transcription-activating element, activates expression of GUS in the dark, and in combination with the G or GTA transcription-activating element activate expression of GUS in the roots of transgenic seedlings (see page 3737). Hence, Puente *et al* have previously disclosed all of the claim limitations.

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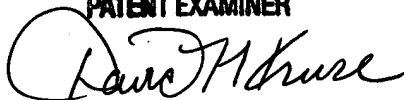
Conclusion

11. This Office action is non-final because it puts forth new grounds of rejection not previously presented.
12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

**DAVID H. KRUSE, PH.D.
PATENT EXAMINER**



David H. Kruse, Ph.D.
28 October 2004

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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